UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

ELI LILLY AND COMPANY,	)	
	)	
Plaintiff,	)	Case No.
	)	
v.	)	
	)	**JURY DEMANDED**
VALHALLA VITALITY LLC,	)	
	)	
Defendant.	)	

PLAINTIFF ELI LILLY AND COMPANY'S COMPLAINT FOR FALSE ADVERTISING AND DECEPTIVE TRADE PRACTICES

1. Defendant Valhalla Vitality LLC ("Valhalla") has designed its website and advertising materials to deceive consumers into believing Valhalla's untested, unapproved drug is safe, effective, and clinically tested and proven to facilitate weight loss and improve blood sugar. In reality, Vitality's drugs are unstudied, unapproved, and potentially dangerous. To mislead patients into taking Valhalla's product, Valhalla falsely attributes clinical trials performed by Plaintiff Eli Lilly and Company ("Lilly") for ***Lilly's*** medicine to Valhalla's own products. Lilly brings this action to protect the public from Valhalla's dangerous, deceptive, and unlawful practices.

2. For nearly 150 years, Lilly has developed and delivered trusted and innovative medicines that save and improve patients' lives. Lilly's proprietary MOUNJARO® and ZEPBOUND® are two first-of-their-kind medicines indicated for serious conditions afflicting millions of Americans. Approximately one in ten Americans have type 2 diabetes, and four in ten Americans are obese. To advance the treatment of these chronic conditions, Lilly used its extensive experience and years of research to develop a new class of medicines that target patients' GLP-1 (glucagon-like peptide-1) and GIP (glucose-dependent insulinotropic polypeptide) receptors. These medicines activate both receptors to improve blood sugar control and reduce

appetite and food intake.[1] FDA has approved these medicines for specific, indicated conditions and populations: MOUNJARO® for adults with type 2 diabetes, and ZEPBOUND® for adults with obesity, moderate to severe obstructive sleep apnea in adults with obesity, or those who are overweight and also have at least one additional weight-related condition, such as hypertension (high blood pressure), dyslipidemia (high cholesterol or fats in blood), type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease.

3. Both MOUNJARO® and ZEPBOUND® contain the active pharmaceutical ingredient tirzepatide. MOUNJARO® and ZEPBOUND® are the *only* FDA-approved medications that contain tirzepatide. Before obtaining FDA approval for MOUNJARO® and ZEPBOUND®, Lilly undertook years of randomized controlled clinical trials evaluating the safety and efficacy of tirzepatide administered by subcutaneous injection on thousands of patients.

4. Unlike MOUNJARO® and ZEPBOUND®, Valhalla's products are not approved, nor even reviewed, by FDA. Valhalla sells and administers compounded drugs that purport to contain tirzepatide from an unknown source. As FDA has warned, "[c]ompounded drugs . . . do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs . . . exposes patients to potentially serious health risks."[2]

5. Nevertheless, Valhalla explicitly represents that its compounded products, which it refers to by the name "Tirzepatide Therapy" (Valhalla's "Unapproved Compounded Drugs") have been the subject of clinical trials and are "proven" to provide the advertised health benefits. Yet

[1] https://web.archive.org/web/20221028212253/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes (archived FDA MOUNJARO® approval press announcement); https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management (FDA ZEPBOUND® approval press announcement).

[2] https://web.archive.org/web/20240803214713/https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers (June 29, 2022 FDA drug compounding FAQ).

Valhalla improper relies on *Lilly's* clinical trials for *Lilly's* FDA-approved MOUNJARO® and ZEPBOUND® to support Valhalla's "proven" efficacy claims for its Unapproved Compounded Drugs, thus rendering literally false Valhalla's claims that its Tirzepatide Therapy product is clinically tested and proven effective.

6. Even more concerning, Valhalla's false and misleading marketing of its Unapproved Compounded Drugs poses a direct patient-safety risk. Valhalla's advertising ensures consumers have no notice of the risks associated with its products and deceives consumers as to the efficacy of those products.

7. FDA has warned that unapproved compounded drugs like the one promoted by Valhalla "pose a higher risk to patients than FDA-approved drugs," such as MOUNJARO® and ZEPBOUND®.[3]

8. Valhalla's false and misleading statements have the tendency to mislead the public and lure individuals with serious health conditions away from safe and effective FDA-approved medicines in favor of untested, compounded drugs. Lilly therefore brings this action for false or misleading advertisement and deceptive practices pursuant to the Lanham Act, 15 U.S.C. §§ 1051 *et seq*. and New York's General Business Law.

THE PARTIES

9. Plaintiff Lilly is a corporation organized and existing under the laws of Indiana and has its principal place of business in Indiana.

10. Defendant Valhalla is a limited liability company organized under the laws of Wyoming, with its principal place of business located at 15801 Cross Bay Blvd., Howard Beach,

[3] https://www.fda.gov/drugs/human-drug-compounding/drug-compounding-and-drug-shortages (FDA explainer on Drug Compounding).

New York 11414. Its registered agent is Business Filings Incorporated, with a registered agent address at 2232 Dell Range Blvd., Ste 200, Cheyenne, Wyoming 82009.

JURISDICTION AND VENUE

11. The Court has subject matter jurisdiction over the Lanham Act cause of action pleaded in this case pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331 and 1338(a). The Court has supplemental jurisdiction over the common law cause of action pleaded herein pursuant to 28 U.S.C. §§ 1338(b) and 1367(a).

12. Valhalla is subject to personal jurisdiction in this District because Valhalla operates and conducts business here, including the unlawful promotion of its Unapproved Compounded Drugs.

13. Valhalla has regular, continuous, and systematic contacts with New York and this District. Valhalla's principal place of business is in Howard Beach, New York, and Valhalla's website provides the Howard Beach address (which is in this District) as its only office location.[4]

14. On information and belief, Valhalla directs its advertising and solicits business through its website, "https://valhallavitality.com." This website is accessible from New York, is directed to New York residents, and has been and, on information and belief, continues to be accessed by New York residents.

15. Valhalla's website offers in-person consultations with a New York-licensed family nurse practitioner at its Howard Beach office in this District.[5]

16. Valhalla's contacts with New York and this District therefore consist of owning and operating a physical storefront in New York and this District, conducting business in New

[4] https://valhallavitality.com/contactus.

[5] https://valhallavitality.com/services/aesthetic-event-at-howard-beach; https://valhallavitality.com/contactus.

York and this District, employing a New York-licensed medical professional to provide services in New York and this District, owning and operating a website accessible in New York and this District, advertising its Unapproved Compounded Drugs to potential customers in New York and this District, and providing functionality for New York residents to schedule an appointment at its location in New York and this District.

17. Venue is proper in this District and division pursuant to 28 U.S.C. § 1391(b)(1) because Valhalla operates and conducts business in this District and Division. Venue is also proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because Valhalla's infringing, unfair, and dangerous marketing has been and is currently directed at consumers in this District.

FACTUAL ALLEGATIONS

I. Lilly's FDA-Approved Tirzepatide Injectable Medications

A. Lilly's History of Producing Safe and Effective Medications

18. Lilly is an international medicine company and pharmaceutical manufacturer. Throughout its nearly 150-year existence, Lilly has pioneered countless life-changing discoveries. Today, Lilly's medicines help tens of millions of patients across the globe, including in New York.

19. Lilly manufactures its medicines under strict controls in state-of-the-art facilities, which employ thousands of highly specialized personnel to ensure that Lilly's medicines meet its rigorous quality and safety standards. Transforming active pharmaceutical ingredients, or API, into medicine is a complex, methodical, and science-based process. Lilly follows Current Good Manufacturing Practices ("CGMP") across the design, monitoring, and control of manufacturing processes and facilities—from establishing robust quality management systems to obtaining quality raw materials and detecting and investigating product quality deviations. Each step—from chemical synthesis of the API to formulation, device assembly, and packaging—requires extensive testing and controls and specialized equipment.

20. Lilly is also subject to—and encourages—FDA oversight and compliance obligations, including routine FDA inspections, adverse event reporting obligations, and post-market surveillance and studies. Additionally, Lilly's medicines must be, and always are, accompanied by important labels, instructions, and warnings, which themselves are approved by FDA.

B. MOUNJARO® and ZEPBOUND®

21. Using its experience and expertise, Lilly developed MOUNJARO® and ZEPBOUND®, which were approved by FDA for sale to the public in 2022 and 2023, respectively. Today, Lilly promotes, offers, and sells MOUNJARO® and ZEPBOUND® throughout New York and the United States, among other geographies.

22. Both MOUNJARO® and ZEPBOUND® contain tirzepatide as their API, which targets both GIP and GLP-1 hormone receptors.

23. Specifically, MOUNJARO® is designed to improve glycemic control in adults with type 2 diabetes mellitus (in addition to diet and exercise). As FDA has noted, "[d]espite the availability of many medications to treat diabetes, many patients do not achieve the recommended blood sugar goals."[6] MOUNJARO® targets this problem head-on. When used as directed, MOUNJARO® has been clinically proven to improve blood sugar control more effectively than other diabetes therapies.

24. ZEPBOUND® is designed to help the millions of American adults with obesity or overweight with weight-related medical problems. As FDA has noted, ZEPBOUND® "addresses an unmet medical need" by targeting "chronic weight management (weight reduction and

[6] https://web.archive.org/web/20221028212253/https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes (archived FDA MOUNJARO® approval press announcement).

maintenance)" through a new method of hormone receptor activation.[7] Accordingly, FDA has indicated ZEPBOUND® to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition, and to treat moderate to severe obstructive sleep apnea in adults with obesity.

25. Lilly exclusively owns the intellectual property rights related to MOUNJARO® and ZEPBOUND® and is the only lawful supplier of those medications.

C. The FDA Approval Process

26. FDA approved MOUNJARO® and ZEPBOUND® pursuant to Lilly's marketing application, itself the culmination of a lengthy clinical trial process designed to develop, study, and bring safe medicines to patients so that—in FDA's words—"American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world."[8] Over the course of nearly a decade, Lilly completed thirty-seven pre-clinical studies and clinical trials for these medicines.

27. MOUNJARO® and ZEPBOUND® are the only FDA-approved medicines containing tirzepatide in the United States.

II. Drug Compounding and Its Inherent Risks

28. Compounding is a "practice in which a licensed pharmacist, a licensed physician or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist,

[7] https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management (FDA ZEPBOUND® approval press announcement).

[8] https://www.fda.gov/drugs/development-approval-process-drugs (FDA explainer of new drug development process).

combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[9]

29. For example, if an individual patient is allergic to an ingredient in an FDA-approved medicine, a compounding pharmacy could produce a version of that medication that does not contain the allergen.

30. As FDA itself makes clear, "[c]ompounded drugs are not FDA-approved."[10] This means FDA does not review compounded drugs to evaluate their safety, effectiveness, or quality before they reach patients. Specifically, unlike FDA-approved medications, compounded drugs are not reviewed and approved by FDA for safety and efficacy. Further, many compounders are not subject to labeling requirements, need not comply with Good Manufacturing Practice regulations, their facilities are not subject to inspections by regulatory authorities, and they have no reporting requirements for adverse events.

31. For that reason, FDA has warned that "[c]ompounded drugs . . . do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs . . . exposes patients to potentially serious health risks."[11] Indeed, FDA recently reiterated that compounded drugs that purport to contain tirzepatide "have not undergone FDA premarket review for safety, effectiveness, and quality, and lack a premarket inspection and

[9] https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding (FDA guidance on drug compounding law compliance).

[10] https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers (FDA drug compounding FAQ).

[11] https://web.archive.org/web/20240803214713/https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers (June 29, 2022 FDA drug compounding FAQ).

finding of manufacturing quality that is part of the drug approval process."[12] Moreover, compounded drugs prepared at state-licensed pharmacies "are not subject to CGMP requirements and are subject to less robust production standards that provide less assurance of quality."[13]

32. For instance, on November 1, 2024, FDA issued a warning about drugs compounded by Fullerton Wellness LLC of California after a patient noticed a black particulate in a vial of Fullerton's compounded semaglutide, and a joint FDA-California investigation uncovered conditions at Fullerton that could cause its drugs, including tirzepatide, to become contaminated.[14]

33. Health risks from compounded drugs are serious. In 2021, a compounding pharmacist pled guilty to providing adulterated compounded drugs to cataract surgery patients. The adulterated compounds contained "an excessive amount of an inactive ingredient" that can damage sensitive eye tissue.[15] At least 68 patients were injected with the adulterated compounds, at two different surgery centers, over a period of months, even though patients suffered near-immediate adverse events, including permanent blindness.[16] One patient had believed "every pill you take, every shot you take is tested" and was surprised to learn that compounded drugs were neither fully tested nor deemed safe or otherwise approved by FDA.[17]

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[12] https://www.fda.gov/media/184606/download (Declaratory Order: Resolution of Shortages of Tirzepatide Injection Products at 10).

[13] *Id.*

[14] https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-patients-and-health-care-professionals-not-use-compounded-drugs-fullerton-wellness.

[15] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/texas-pharmacist-pleads-guilty-adulterating-drug-used-cataract-surgeries (FDA press announcement re guilty plea).

[16] https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097 (WFAA article re outbreak).

[17] *Id.*

34. Lilly has seen problems firsthand for compounded tirzepatide. Lilly has discovered compounded drugs advertised as tirzepatide with safety, sterility, and efficacy problems. Some contain bacteria, high impurity levels, low potency levels, different colors (pink, instead of colorless), or a chemical structure different from the tirzepatide in Lilly's FDA-approved medicines. In at least one instance, Lilly saw nothing more than sugar alcohol.

35. Consequences from compounded drugs may be deadly. In October 2012, compounded drugs contaminated with a fungus were shipped throughout the country and later injected into patients' spines and joints. After these contaminated products were injected into nearly 14,000 patients, more than 60 people died of fungal meningitis.[18] Afterwards, FDA commented:

> The 2012 fungal meningitis outbreak was not an isolated event. It was the most serious in a long history of serious adverse events associated with contaminated, super-potent, mislabeled, or otherwise poor quality compounded drugs. In addition, many serious adverse events linked to poor quality compounded drugs, including outbreaks of infections and deaths have occurred since then. And, because most compounders do not report adverse events to FDA, the agency may not be aware of adverse events associated with compounded drugs unless a health care provider submits an adverse event report regarding his or her patients or a state official notifies FDA.[19]

Company executives were convicted and received sentences of up to 14 years in prison.[20]

36. There are countless other examples of people experiencing serious injury from taking unregulated medicines. Inappropriate drug compounding caused at least 73 reported compounding errors between 2001 and 2019. These errors led to more than 1,562 adverse events

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[18] *Id.*

[19] https://www.fda.gov/media/102493/download (FDA Compounding Progress Report).

[20] https://www.justice.gov/usao-ma/pr/former-owner-defunct-new-england-compounding-center-resentenced-14-years-prison. (DOJ press release on compounder prison sentence)

and at least 116 deaths.[21] There are also instances of close calls, particularly for sterile injectables. For example, in 2022 FDA inspected 503A pharmacy North American Custom Laboratories, LLC d/b/a FarmaKeio Superior Custom Compounding and found that it "routinely use[d] non-pharmaceutical grade components for compounding drug products" and "[n]on-sterilized equipment . . . in sterile drug production,"[22] and issued a warning letter—that appears to be unresolved—for "serious deficiencies in . . . practices for producing drug products intended or expected to be sterile, which put patients at risk."[23] As a result of these findings, FDA also recommended a voluntary recall of all of FarmaKeio's unexpired drug products that are intended to be sterile.[24]

37. These risks have extended to compounded tirzepatide.

38. Given the popularity of Lilly's MOUNJARO® and ZEPBOUND® medicines, numerous businesses, including Valhalla, have begun to manufacture and/or market unapproved compounded products purportedly featuring tirzepatide.

39. As this conduct has become more prevalent, government agencies have warned the public as to the risks of such products. For instance, in July 2024, FDA sent a letter to compounding advocacy organizations warning that it has received "reports describing patients who

[21] *Id.*

[22] https://www.fda.gov/media/160771/download (Form FDA 483 to N. Am. Custom Labs., LLC d/b/a FarmaKeio Superior Custom Compounding (Mar. 10, 2022)).

[23] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/north-american-custom-laboratories-llc-dba-farmakeio-superior-custom-compounding-642792-11182022 (Warning Letter from Div. of Pharma. Quality Op. II to J. Graves, Vice President, N. Am. Custom Labs., LLC d/b/a FarmaKeio Superior Custom Compounding (Nov. 18, 2022)).

[24] https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-patients-and-health-care-professionals-not-use-sterile-products-north-american-custom (FDA notice of voluntary recall).

experienced adverse events following the administration of compounded . . . tirzepatide."[25] FDA reiterated that "compounded drug products, including compounded . . . tirzepatide products, are not FDA-approved. They do not undergo premarket review by FDA for safety, effectiveness, or quality."[26] Further, an October 2024 FDA statement warned of "multiple reports of adverse events, some requiring hospitalization, that may be related to dosing errors."[27] Unsurprisingly, poison control centers across the United States have also reported a troubling trend, seeing "a nearly 1,500% increase in calls since 2019 related to overdose or side effects of injectable weight-loss drugs."[28] On January 3, 2025, the South Carolina Attorney General and Illinois Attorney General each issued warnings against compounded tirzepatide drugs. South Carolina Attorney General echoed FDA's warnings that "[u]napproved and compounded products can be risky for consumers because they are not reviewed by FDA for safety, quality, or effectiveness," expressing concern about "unscrupulous sellers [who] are making misleading health claims and promoting unapproved and compounded tirzepatide . . . products in formulations that have never been evaluated by any regulatory agency and may never have been tested in humans at all."[29] Similarly, the Illinois Attorney General warned "about misleading advertising by med spas, wellness centers, online

[25] https://www.pa.gov/content/dam/copapwp-pagov/en/dos/department-and-offices/bpoa/nursing/fda-safety-alert.pdf (July 16, 2024 FDA letter sent to the Alliance for Pharmacy Compounding and the Outsourcing Facility Association).

[26] *Id.*

[27] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss (Oct. 2, 2024 FDA statement on Unapproved GLP-1 Drugs).

[28] https://poisoncenters.org/track/GLP-1 (Poison Centers report on incretin overdoses).

[29] https://www.scag.gov/about-the-office/news/consumer-alert-attorney-general-alan-wilson-warns-consumers-to-be-cautious-when-purchasing-unapproved-and-compounded-weight-loss-medications/#.

retailers and social media sellers . . . offering compounded drugs" that are not "review[ed] . . . for safety, quality or effectiveness . . . and . . . may pose health risks."[30]

40. Leading health organizations have also expressed concern. Earlier this year, the Obesity Society, Obesity Action Coalition, and Obesity Medicine issued a joint statement regarding compounded GLP-1 medicines, stating, "[u]nfortunately, many of the available alternatives [to GLP-1 therapies], like compounded versions of semaglutide and tirzepatide, are not what they are advertised to be."[31]

41. The issue of unsafe compounded drugs purporting to contain tirzepatide has also received international attention. Australia recently banned the development and sale of compounded anti-obesity medications because of "increasing community concern" and "increasing reports of patients coming to harm from" compounded drugs promoted to aid with weight loss.[32] The ban—effective October 2024—targets compounded drugs that are "being misrepresented and sold as replica [] Mounjaro®."[33] As Mark Butler, Australia's Minister for Health, said, "Australians should be able to have faith in the medications they use, including compounded medicines," and the ban "will protect Australians from harm and save lives."[34]

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[30] https://www.illinoisattorneygeneral.gov/news/story/updated-consumer-alertattorney-general-raoul-reminds-illinois-residents-to-be-vigilant-when-seeking-glp-1-drugs-for-weight-loss.

[31] https://obesitymedicine.org/blog/leading-obesity-expert-organizations-release-statement-to-patients-on-glp-1-compounded-alternatives/ (Joint Statement on Compounded GLP-1 Alternatives).

[32] https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/protecting-australians-from-unsafe-compounding-of-replica-weight-loss-products (Australia Minister for Health and Aged Care press release).

[33] *Id.*

[34] *Id.*

III. Valhalla's False and Misleading Claims

42. Valhalla purports to be a health and wellness center located in Howard Beach, New York.

43. As part of its services, Valhalla promotes (and encourages potential customers to use) non-FDA-approved, compounded tirzepatide as a claimed weight loss treatment it calls "Tirzepatide Therapy," *i.e.* its Unapproved Compounded Drugs. In particular, Valhalla claims its "once-weekly injections" of Tirzepatide Therapy "require no change in diet or lifestyle to produce weight loss results of greater than 50 lb in as little as 6 months."[35]

Buy Tirzepatide online

Tirzepatide injections are GLP-1 agonist medications used to treat obesity and aid in dramatic weight loss. Tirzepatide are both once-weekly injections that require no change in diet or lifestyle to produce weight loss results of greater than 50 lb in as little as 6 months. When used along with an individualized low-calorie, low-fat diet and exercise program to help with weight loss, overweight adults who may also have high blood pressure, diabetes, or high cholesterol see significant progress across all health markers. Tirzepatide injections are a class of medications called glucagon-like-peptide-1 (GLP-1) agonists, although Tirzepatide has enhanced effects as a glucose-dependent insulinotropic polypeptide (GIP) agonist that produce more drastic weight loss results.

44. As set forth in detail below, Valhalla has made and continues to make numerous false statements throughout its advertising pertaining to the inherent quality of its Unapproved Compounded Drugs, including statements that state or necessarily imply that Valhalla's Unapproved Compounded Drugs have been proven safe and effective for weight loss. These false and misleading statements go to the inherent nature of Valhalla's Unapproved Compounded Drugs and deceive consumers as to the nature and quality of Valhalla's unapproved and untested drugs.

45. A compilation of certain of Valhalla's false and misleading advertising are discussed below and are attached hereto as **Exhibit A**.

[35] https://valhallavitality.com/product/tirzepatide-therapy.

46. Valhalla's website, located at https://valhallavitality.com, offers its "Tirzepatide Therapy" with a subscription.[36]

47. In promoting the "Tirzepatide Therapy," Valhalla also prominently displays a vial labeled appearing to contain "[vitamin] B6." Moreover, several patients have reported via Reddit that the Tirzepatide Therapy they received from Valhalla contained vitamin B12, a common additive among compounding pharmacies. (Several others have also reported having "their credit card info compromised directly after purchases from Valhalla, with users expressing that they hoped Valhalla "add[ed] b6 or something not identity theft."[37])

48. Valhalla then promotes the safety and efficacy of its "Tirzepatide Therapy" by discussing studies of ***Lilly's*** medicines on its website when making statements that expressly state

[36] https://valhallavitality.com/product/tirzepatide-therapy.

[37] https://www.reddit.com/r/tirzepatidecompound/comments/1g17xhc/psa_valhalla_vitality_billingwebsite_is/?rdt=61098.

or necessarily imply that its Unapproved Compounded Drugs are FDA-approved medications clinically proven to achieve certain therapeutic outcomes. Lilly's clinical trials have no bearing on, and cannot substantiate claims about, Valhalla's Unapproved Compounded Drugs, which upon information and belief are sold without having undergone ***any*** testing for safety or effectiveness in achieving any of the therapeutic outcomes claimed.

49. For example, Valhalla references clinical trials on its website and expressly claims: "In clinical trials, ***Tirzepatide Therapy*** was found to be safe and effective for reducing HbA1c levels by up to 1.7%."[38]

> Tirzepatide works by stimulating both GLP-1 and glucagon receptors on pancreatic beta cells, which leads to increased insulin release into the bloodstream. In clinical trials, Tirzepatide Therapy was found to be safe and effective for reducing HbA1c levels by up to 1.7%.

50. Valhalla also implies through its website that its Unapproved Compounded Drugs are clinically tested and verified to be safe and effective in helping "to treat obesity and aid in dramatic weight loss":[39]

> **Buy Tirzepatide online**
>
> **Tirzepatide injections are GLP-1 agonist medications used to treat obesity and aid in dramatic weight loss. Tirzepatide are both once-weekly injections that require no change in diet or lifestyle to produce weight loss results of greater than 50 lb in as little as 6 months. When used along with an individualized low-calorie, low-fat diet and exercise program to help with weight loss, overweight adults who may also have high blood pressure, diabetes, or high cholesterol see significant progress across all health markers. Tirzepatide injections are a class of medications called glucagon-like-peptide-1 (GLP-1) agonists, although Tirzepatide has enhanced effects as a glucose-dependent insulinotropic polypeptide (GIP) agonist that produce more drastic weight loss results.**

51. Likewise, Valhalla boasts that its Tirzepatide Therapy "may offer a unique advantage over other treatments for diabetes"; "allows for greater control over insulin secretion and glycemic control without additional risk of hypoglycemia or weight gain typically associated

[38] https://valhallavitality.com/product/tirzepatide-therapy.

[39] *Id.*

with traditional therapies"; and "has quickly become a promising option for those looking for an effective way to manage their diabetes with minimal side effects."[40]

52. These statements expressly communicate to consumers that Valhalla's Unapproved Compounded Drugs have been clinically tested and shown to facilitate weight loss, yet no such clinical trials have actually been conducted. They also suggest that Valhalla's products are effective in treating diabetes.

53. Valhalla's references to clinical trials are clear establishment claims. An establishment claim (*i.e.*, a "tests prove" type of claim) must be supported by the kind of testing described in the advertisement. If the advertiser lacks the testing discussed in its advertising, its claims are false. Here, Valhalla's advertising expressly and repeatedly references clinical trials in discussing the safety and efficacy of its Unapproved Compounded Drugs—*i.e.*, the Tirzepatide Therapy (likely consisting of tirzepatide injections mixed with vitamins B6 or B12). Thus, Valhalla must have clinical studies proving that its "Tirzepatide Therapy" is safe and effective at weight loss and improving blood sugar. Upon information and belief, Valhalla does not have any clinical data assessing the safety or effectiveness of its compounded Tirzepatide Therapy.

54. Further, Valhalla cannot rely on Lilly's clinical trials for its FDA-approved MOUNJARO® and ZEPBOUND® to support its claims about Valhalla's "Tirzepatide Therapy" because MOUNJARO® and ZEPBOUND® are proprietary medicines that have nothing to do with Valhalla's "Tirzepatide Therapy." Thus, Lilly's clinical studies are irrelevant to the safety and efficacy of Valhalla's Unapproved Compounded Drugs.

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[40] *Id.*

55. In short, throughout its advertising, Valhalla makes a series of false and misleading claims that explicitly communicate that its Unapproved Compounded Drugs—so-called "Tirzepatide Therapy"—have been clinically tested and backed by specific scientific research to provide safe and effective weight loss benefits. These statements—individually and collectively—communicate to prospective purchasers that Valhalla's untested and unapproved drugs are proven safe and effective for the treatment of that person's type 2 diabetes or obesity and provide better outcomes than Lilly's FDA-approved tirzepatide medicines. Quite the contrary: no regulator—let alone FDA—has evaluated the safety or effectiveness of Valhalla's Unapproved Compounded Drugs. Lilly is unaware of any data supporting Valhalla's representation that its Unapproved Compounded Drugs are safe and effective.

56. Valhalla's false statements are intended to—and likely—cause confusion, mistake, or deceive consumers as to the nature and quality of Valhalla's Unapproved Compounded Drugs. Further, these statements present a significant patient safety risk, as these statements have the tendency to draw the public away from using safe, effective, FDA-approved medicines and encourage the use of untested, unapproved compounded drugs.

IV. Harm from Valhalla's Conduct

57. Valhalla's false, misleading, and reckless promotion and sale of its Unapproved Compounded Drugs has harmed Lilly and consumers and will continue to do so if left unchecked.

58. First, Valhalla's misrepresentations are intended to lure consumers away from obtaining safe and effective treatment with MOUNJARO® or ZEPBOUND® on the false promise that Valhalla's Unapproved Compounded Drugs are as effective in helping people treat diabetes and address weight-related medical problems. This not only has and will continue to result in lost sales for Lilly, but more importantly risks severe harm to consumers—at best financially, but potentially far worse given the unapproved and untested nature of Valhalla's products.

59. Second, Valhalla's misrepresentations cause irreparable damage to Lilly's brand and customer goodwill by placing consumers at an impermissibly elevated risk of harm. Should injury befall one of Valhalla's patients, Valhalla's false and misleading advertising is likely to confuse consumers, who will undoubtedly draw negative inferences as to Lilly's medicines as well.

FIRST CAUSE OF ACTION
False and Misleading Advertising and Promotion
in Violation of 15 U.S.C. § 1125(A)(1)(B)

60. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

61. Valhalla's commercial advertising claims described herein are false and misleading in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

62. Valhalla has knowingly and willfully made materially false and misleading statements in its commercial advertisements for its Unapproved Compounded Drugs (including its website and social media). These statements regarding alleged clinical studies on the safety, quality, and effectiveness of Valhalla's Unapproved Compounded Drugs have influenced and are likely to continue to influence consumers' purchasing decision—specifically, the decision to purchase Valhalla's Unapproved Compounded Drugs instead of Lilly's FDA-approved medicines. As a result, Valhalla is steering individuals with serious diseases like diabetes and obesity away from obtaining safe, effective, available, and FDA-approved treatments. Valhalla's unlawful conduct is putting health, safety, and lives at risk.

63. Valhalla has caused its false statements to enter interstate trade or commerce.

64. As a direct and proximate result of Valhalla's false and deceptive campaign, Lilly is suffering immediate and continuing, competitive irreparable injury for which there is no adequate remedy at law.

65. As a direct and proximate result of Valhalla's false and deceptive campaign, Lilly has suffered and will continue to suffer significant monetary damages and discernible competitive injury by the loss of goodwill.

66. This is an exceptional case under 15 U.S.C. § 1117.

67. Lilly is entitled to injunctive relief as well as monetary damages, and other remedies provided by Sections 1116, 1117, and 1118, including Valhalla's profits, treble damages, reasonable attorneys' fees, costs, and prejudgment interest.

SECOND CAUSE OF ACTION
Deceptive Acts or Practices
in Violation of New York Gen. Bus. Law § 349

68. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

69. The New York General Business Law Section 349 ("GBL § 349") declares unlawful "[d]eceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service in this state."

70. Valhalla falsely advertises and markets their Unapproved Compounded Drugs to consumers.

71. Valhalla's improper consumer-oriented conduct is deceptive in a material way by, among other things, advertising that its tirzepatide product is clinically tested to provide safe and effective weight loss benefits.

72. As a direct and proximate result of Valhalla's unlawful campaign, Valhalla has put the safety of New Yorkers (and other American consumers) at risk with its untested and unapproved products. Additionally, Lilly has suffered and will continue to suffer significant injury by the loss of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® tirzepatide medicines.

73. As a direct and proximate result of Valhalla's unlawful campaign, Valhalla has unfairly benefitted and profited from sales it made as a result of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® tirzepatide medicines.

74. Valhalla is liable to Lilly for damages in amounts to be proven at trial, including attorneys' fees, costs, and treble damages, as well as any other remedies the Court may deem appropriate under GBL § 349.

THIRD CAUSE OF ACTION
False Advertising
in Violation of New York Gen. Bus. Law § 350

75. Lilly repeats and realleges each and every allegation above as if fully set forth herein.

76. The New York General Business Law Section 350 ("GBL § 350") declares unlawful "[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state."

77. Valhalla falsely advertises and markets their Unapproved Compounded Drugs to consumers.

78. Valhalla's improper consumer-oriented conduct is deceptive in a material way by advertising, among other things, that its tirzepatide product is clinically tested to provide safe and effective weight loss benefits.

79. As a direct and proximate result of Valhalla's unlawful advertising, Valhalla has put the safety of New Yorkers (and other American consumers) at risk with its illegal products. Additionally, Lilly has suffered and will continue to suffer significant injury by the loss of goodwill associated with Lilly's MOUNJARO® and ZEPBOUND® tirzepatide medicines.

80. Valhalla is liable to Lilly for damages in amounts to be proven at trial, including attorneys' fees, costs, and treble damages, as well as any other remedies the Court may deem appropriate under GBL § 350.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Lilly prays that this Court enter judgment in its favor on its claim for relief set forth above and award it relief including, but not limited to, the following:

1. An Order declaring that Valhalla:

   a. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a);

   b. Engaged in deceptive acts or practices, in violation of GBL § 349;

   c. Engaged in deceptive acts or practices, in violation of GBL § 350;

   d. That each of the above acts was willful and knowing.

2. An injunction permanently enjoining and restraining Valhalla and its officers, agents, servants, employees, and attorneys and all persons acting in concert or participation with any of them, from:

   a. Falsely stating or suggesting that Valhalla's Unapproved Compounded Drugs have been the subject of clinical studies or achieve certain therapeutic outcomes;

   b. Engaging in any unfair competition with Plaintiff Lilly; and

   c. Engaging in any deceptive or unfair acts.

3. An Order requiring Valhalla and its officers, agents, servants, employees, and attorneys and all persons acting in concert or participation with any of them, to engage in corrective advertising by informing consumers that:

a. Valhalla's Unapproved Compounded Drugs are not MOUNJARO® or ZEPBOUND®;

b. Valhalla's Unapproved Compounded Drugs are not the same as MOUNJARO® or ZEPBOUND®;

c. Valhalla's Unapproved Compounded Drugs are not and have never been approved by FDA;

d. Valhalla's Unapproved Compounded Drugs have never been studied in clinical trials;

e. Valhalla's Unapproved Compounded Drugs have never been demonstrated to be safe or effective; and

4. An Order directing Valhalla to file with this Court and serve on Lilly's attorneys, thirty (30) days after the date of entry of any injunction, a report in writing and under oath setting forth in detail the manner and form in which it has complied with the Court's injunction.

5. An Order requiring Valhalla to account for and pay to Lilly any and all profits arising from the foregoing acts of false advertising.

6. An Order requiring Valhalla to pay Lilly compensatory damages in an amount as yet undetermined caused by the false advertising and trebling such compensatory damages for payment to Lilly in accordance with 15 U.S.C. § 1117, GBL § 349, GBL § 350, and other applicable laws.

7. An Order for pre-judgment and post-judgment interest on all damages.

8. An Order requiring Valhalla to pay Lilly's costs and attorney fees in this action pursuant to 15 U.S.C. § 1117, GBL § 349, GBL § 350, and any other applicable provision of law.

9. Other relief as the Court may deem appropriate.

JURY DEMAND

Lilly hereby demands a jury trial for all issues so triable.

Dated: January 13, 2025

Respectfully submitted,

/s/ Michael A. Glick

Michael A. Glick

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